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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/090,215	03/04/2002	Adrienne Elizabeth Dubin	ORT-1601	5197

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EXAMINER	
LOCKARD, JON MCCLELLAND	
ART UNIT	**PAPER NUMBER**
1647	

DATE MAILED: 06/06/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/090,215	DUBIN ET AL.	
	Examiner	Art Unit	
	Jon M. Lockard	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 March 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *11 and 23* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *11 and 23* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *04 March 2002* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *2/10/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Status of Application, Amendments, and/or Claims

1. The Amendment filed 23 March 2005 has been received and entered in full. Claims 11 and 23 have been amended. Therefore, claims 11 and 23 are pending and the subject of this Office Action.

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Information Disclosure Statement

3. The Information Disclosure Statement (IDS) submitted on 10 February 2005 has been considered by the Examiner.

Withdrawn Objections and/or Rejections

4. The objection to the drawings as set forth at page 2 (¶5) in the previous Office Action (mailed 23 December 2004) is withdrawn in view of Applicant's arguments (filed 23 March 2005).

5. The objection to the Specification as set forth at page 3 (¶7) in the previous Office Action (mailed 23 December 2004) is withdrawn in view of Applicant's amendments (filed 23 March 2005).

6. The rejection of claims 11 and 23 under 35 U.S.C. §112(2), as set forth at pages 7-8 (¶17-20) in the previous Office Action (mailed 23 December 2004) is withdrawn in view of

Applicants amendment of claims 11 and 23 which now recite "the amino acid sequence" and "consists of the amino acid sequence", respectively (filed 23 March 2005).

7. The rejection of claims 11 and 23 under 35 U.S.C. §102(e) as being anticipated by Masters et al., as set forth at page 8 (¶21-23) in the previous Office Action (mailed 23 December 2004) is withdrawn in view of Applicant's amendment of claims 11 and 23 which now recite "comprising the amino acid sequence set forth in SEQ ID NO:12" and "wherein the protein consists of the amino acid sequence set forth in SEQ ID NO:12", and in view of Applicant's arguments set forth at pages 7-8 of the response (filed 23 March 2005).

Maintained Objections and/or Rejections

Claim Rejections - 35 USC § 101 and 35 USC § 112, 1st Paragraph

8. Claims 11 and 23 remain rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific and substantial asserted utility, or a well established utility, for reasons set forth at pages 3-7 (¶ 8-16) in the previous Office Action (mailed 23 December 2004).

9. The instant application discloses a polypeptide set forth as SEQ ID NO:12. The Specification teaches that SEQ ID NO:12 is one of three isoforms of the putative human vanilloid receptor identified as VR3A+B+ (See page 7, lines 26-27). The specification asserts that predicted amino acid sequence of VR3A+B+ set forth as SEQ ID NO:12 displays sequence homology and structural homology to the vanilloid receptor family (VR1 and VR2) (See page 8, lines 15-20 and page 49, line 28 – page 50, line 6). The only experimental data or information provided by the Instant Specification on whether the putative VR3A+B+ protein (SEQ ID

NO:12) functions like an ion channel is the disclosure that oocytes injected with VR3A+B+ RNA demonstrated enhancement of a heat-induced response (measured by whole cell currents) compared to controls (See Figure 10, page 5, line 17 – page 6, line 15). However, mere homology and a showing of increased responsiveness to heat would not be accepted by those of skill in the art as being predictive of function. For example, the Specification teaches that VR1 is activated by capsaicin and RTX, and activation of VR1 is blocked by the antagonists capsazepine and ruthenium red (See page 1, line 28 – page 2, line 2). However, the Instant Specification discloses that oocytes injected with VR3A+B+ RNA (encoding the claimed protein of SEQ ID NO:12) demonstrated no detectable differences in membrane conductance when compared to controls when challenged with a variety of ligands (including capsaicin and RTX), low pH, and depolarizing as well as hyperpolarizing voltage steps (See page 41, lines 22-25, Table 1). Therefore, the Specification's assertion that SEQ ID NO:12 functions as member of the vanilloid receptor family is not a substantial assertion of utility, since significant further research would be required of the skilled artisan to determine the function and/or biological activity of the putative receptor. There is no well-established utility for a specific nucleic acid or amino acid sequence, and the specification fails to disclose a specific and substantial utility for the claimed invention.

10. Applicant's arguments (filed 23 March 2005), as they pertain to the rejections have been fully considered but are not found to be persuasive for the following reasons. In the previous Office Action of 23 December 2004, the Examiner made a *prima facie* showing that the claimed invention lacks utility and provided sufficient evidentiary basis for factual assumptions relied upon in establishing the *prima facie* showing (see pages 3-7). Essentially, Applicant has not

provided evidence to demonstrate that the claimed VR3 polypeptide of the instant application is supported by a specific and asserted utility or a well-established utility. The Examiner has fully considered all evidence of record and has responded to each substantive element of Applicant's response. It is noted to Applicant that MPEP § 2107.02 (part VI) also states that "only where the totality of the record continues to show that the asserted utility is not specific, substantial, and credible should a rejection based on lack of utility be maintained".

11. Applicants assert at page 6 of the response (filed 23 March 2005) that the claimed protein may be used to identify modulators of the VR3 receptor, which should have utility as therapeutic agents in treating certain medical conditions or diseases, such as pain. Thus, Applicants assert, a real-world utility specific to the claimed polypeptide has been identified.

12. Applicant's arguments have been fully considered but they are not persuasive. As set forth at page 5 (¶ 12-13) of the previous Office Action, the specification neither identifies the biological functions of the claimed protein, nor any diseases that are associated with the claimed protein. Without any biological activity or link to a specific disease, further research would be required to determine the properties of the claimed VT3 protein of SEQ ID NO:12, or to identify a disease that can be treated or diagnosed with the claimed molecules, which is insufficient to meet the requirement of 35 USC § 101. Furthermore, since the specification has not taught any specific disease that can be treated with the claimed VR3 receptor protein, it follows that it has not taught any specific disease that can be treated with compounds that modulate the VR3 receptor protein.

13. Applicants assert at pages 6-7 of the response (filed 23 March 2005) that the specification provides evidence of several biological properties of hVR3 and its associated protein, including experimental results reflecting that all three isoforms of VR3 function to enhance heat-induced responses. The Applicants then assert that artisans would not doubt the asserted utility in light of sequence homology of the claimed protein to known members of the TRPV subfamily coupled with the showing of increased responsiveness to heat, and members of the subfamily appear to be involved in the sensation of pain-producing heat.

14. Applicant's arguments have been fully considered but they are not persuasive for the following reasons. As set forth at page 5 (¶ 12-13) of the previous Office Action, mere sequence homology and a showing of increased responsiveness to heat would not be accepted by those of skill in the art as being predictive of function. For example, the Specification teaches that VR1 is activated by capsaicin and RTX, and activation of VR1 is blocked by the antagonists capsazepine and ruthenium red (See page 1, line 28 – page 2, line 2). However, the Instant Specification discloses that oocytes injected with VR3A+B+ RNA (encoding the claimed protein of SEQ ID NO:12) demonstrated no detectable differences in membrane conductance when compared to controls when challenged with a variety of ligands (including capsaicin and RTX, known agonists of vanilloid receptors), low pH, and depolarizing as well as hyperpolarizing voltage steps (See page 41, lines 22-25, Table 1). The negative results of the functional assays presented in the Specification are not indicative of any function, and no disease or disorder is correlated with the polypeptide. While homology to known members of the TRPV subfamily and an increased responsiveness to heat is an interesting scientific finding, it is not sufficient to establish a real-world use for the claimed protein. In fact, Applicant's assert at page 7 of the

response that "That different members of the TRPV subfamily have different properties of functions (as noted in the specification) is of little import, however, since it follows from the fact that they are not identical". The Examiner fully agrees with this statement, which is why it was stated at page 5 of the previous Office Action that, while it is credible that SEQ ID NO:12 is a member of the TRP/vanilloid family of ion channels, its identification as such is not sufficient to establish either a well-known, or a specific and substantial utility. The use of a putative ion channel to discover its biological properties does not constitute a specific, substantial utility, but rather is further experimentation to determine the properties of that which is being claimed. Therefore, the Specification's assertion that SEQ ID NO:12 functions as member of the vanilloid receptor family is not a substantial assertion of utility, since significant further research would be required of the skilled artisan to determine the function and/or biological activity of the putative receptor.

15. There is little doubt that, after complete characterization, this protein may be found to have a specific and substantial credible utility. This further characterization, however, is part of the act of invention and until it has been undertaken, Applicant's claimed invention is incomplete. The instant situation is directly analogous to that which was addressed in *Brenner v. Manson*, 148 U.S.P.Q. 689 (Sus. Ct, 1966), in which a novel compound which was structurally analogous to other compounds which were known to possess anti-cancer activity was alleged to be potentially useful as an anti-tumor agent in the absence of evidence supporting this utility. The court expressed the opinion that all chemical compounds are "useful" to the chemical arts when this term is given its broadest interpretation. However, the court held that this broad interpretation was not the intended definition of "useful" as it appears in 35 U.S.C. §101, which

requires that an invention must have either an immediately obvious or fully disclosed "real world" utility. The court held that:

> "The basic quid pro quo contemplated by the Constitution and the Congress for granting a patent monopoly is the benefit derived by the public from an invention with substantial utility", "[u]nless and until a process is refined and developed to this point-where specific benefit exists in currently available form-there is insufficient justification for permitting an applicant to engross what may prove to be a broad field", and "a patent is not a hunting license", "[i]t is not a reward for the search, but compensation for its successful conclusion."

16. The instant claims are drawn to a protein which has undetermined function or biological significance. Until some actual and specific activity or significance can be attributed to the protein identified in the specification as SEQ ID NO:12, the claimed invention is incomplete.

17. It is believed that all pertinent arguments have been addressed.

Claim Rejections - 35 USC § 112, 1st Paragraph

18. Claims 11 and 23 also remain rejected under 35 U.S.C. 112, first paragraph for reasons set forth at page 7 (¶16) of the previous Office Action (mailed 23 December 2004). Specifically, since the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

Summary

19. No claim is allowed.

20. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Jon M. Lockard, Ph.D.** whose telephone number is **(571) 272-2717**. The examiner can normally be reached on Monday through Friday, 8:00 AM to 6:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, **Brenda Brumback**, can be reached on **(571) 272-0961**.

The fax number for the organization where this application or proceeding is assigned is **571-273-8300**.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see **http://pair-direct.uspto.gov**. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at **866-217-9197** (toll-free).

JML
May 21, 2005

LORRAINE SPECTOR
PRIMARY EXAMINER